

Application No. 10/735,645

REMARKS

Applicant has carefully studied the outstanding Official Action mailed on November 4, 2004. This response is intended to be fully responsive to all points of rejection raised by the Examiner and is believed to place the application in condition for allowance. Favorable reconsideration and allowance of the application are respectfully requested.

The drawings stand objected under 37 CFR 1.84(9)(4) because the drill has been inadvertently labeled 30, which is the reference number for the facet prosthesis. The specification on page 5 and Fig. 3 have been amended so the drill is now labeled 30'.

Claims 1-5 stand rejected under 35 USC §102(b) as being anticipated by Branemark (US Patent 5,171,284).

Claim 6 stands rejected under 35 USC §103(a) as being unpatentable over Branemark.

Claim 6 stands rejected under 35 USC §103(a) as being unpatentable over Branemark in view of Lundborg (US Patent 6,342,076).

Examiner states that in Branemark, the elastomeric "cushion expands outward when the ends move together (see Fig. 2)."

Applicant respectfully traverses this argument. The movement in the present invention that causes radial expansion of the cushion is axial compression of the cushion caused by axial movement of the fasteners towards each other and against the cushion. In Fig. 2 of Branemark, the cushion is not under axial compression and the fasteners do not move axially towards each other. Rather one of the fasteners merely moves together with the finger in which it is inserted and the cushion bulges to one side. Claim 1 has been amended to clearly recite this structural difference over Branemark.

Examiner states that in Branemark, "bone material...enters the sleeve and acts as a wedge to expand it."

Applicant respectfully traverses this argument. In the claims, the prosthesis comprises the wedge and the wedge has been positively recited in the claims (claim 4) as part of the prosthesis. In Branemark, the prosthesis has no wedge. The bone material is not part of the prosthesis and under 35 USC 101, part of the human body cannot be recited as part of the claimed invention. Thus, Branemark does not anticipate claim 4. Claim 4 has been rewritten in independent form.

Regarding the rejection of claim 6, Applicant respectfully maintains that the rejections is not proper under 35 USC §103(a).

Application No. 10/735,645

The basic considerations that apply to obviousness rejections under MPEP §2141 are as follows:

- a) the claimed invention must be considered as a whole;
- b) the references must be considered as a whole and must suggest the desirability and thus the obviousness of making the combination;
- c) the references must be viewed without the benefit of impermissible hindsight vision afforded by the claimed invention; and
- d) reasonable expectation of success is the standard by which obviousness is determined.

When the prior art itself fails to meet **even one** of the above criteria the cited art does not satisfy 35 USC §103(a) and prevents the establishment of the required *prima facie* case of obviousness by the Examiner. See In re Oetiker, 977 F.2d 1443, 1445 (Fed. Cir. 1992); see also In re Rijckaert, 28 USPQ2d 1955, 1956 (Fed. Cir. 1993). Moreover, to establish the required case of *prima facie* obviousness, the Examiner is required to demonstrate that the prior art discloses or suggests all the critical elements of the invention, without reference to applicants' specification, and that the existence of these elements enables one skilled in the art to practice the invention. See In re Vaeck, 947 F.2d 488 (Fed. Cir. 1991).

Moreover, if the prior art methodology must be modified in any way to practice the instant invention the prior art citation must *also* render obvious these modifications or provide a reasonable expectation for the successful practice of the invention with the necessary modifications.

The Examiner cites In re Leshin, 125 USPQ 416, regarding choice of material. The elastomeric balls recited in claim 6 are not a material choice – they are structurally different than the elastomeric cushion shown in Branemark. Branemark does not teach nor does he contemplate using elastomeric balls sealed in a lumen with end caps. This structure is thus not at all obvious in light of Branemark. Claim 6 has been rewritten in independent form.

Claims 2 and 3 have been canceled as reciting material now in amended claim 1. Claim 7 has been amended to depend from claim 4.

Application No. 10/735,645

It is accordingly respectfully submitted that claims 1 and 4-8 are in a condition for allowance.

Applicant respectfully requests that a timely Notice of Allowance be issued in this case.

Respectfully submitted,
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(Name of Applicant's Representative)

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(Signature)

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